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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DLA PIPER RUDNICK GRAY CARY US, LLP 2000 UNIVERSITY AVENUE E. PALO ALTO, CA 94303-2248				
			EXAMINER RAGONESE, ANDREA M	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,641

Applicant(s)

JACOBS ET AL.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8,11-13,16,21,24-26,46-50 and 54-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,11-13,16,21,24-26,46-50 and 54-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Amendment***

1. The amendment filed on October 25, 2004 has been entered. Examiner acknowledges that **claims 1, 48 and 50** have been amended, and **claims 4-7, 10, 14-15, 17-19, 23, 51-53 and 59-61** have been canceled.

Response to Arguments

2. Applicant's arguments, with respect to the 102(b) rejection of **claims 1, 2, 13, 16, 21, 24-26 and 54**, filed October 25, 2004 (see pages 6-7), have been fully considered but they are not persuasive. Regarding the amended claim limitation in **claim 1** stating "in a non-orthogonal manner" and Applicant's argument that the prior art of record—Goble (US 5,352,229)—"does not teach or suggest the combination of a supportive backing and through-hole, with at least one attachment point extending from the backing in a non-orthogonal manner." The Examiner respectfully disagrees with this statement. The device has a supportive backing **31** with at least one through-hole **33, 34** formed therethrough and at least one attachment point **35** extending from the backing **31**, (column 5, lines 55-68), as shown in Figure 2. The attachment point **35** extends from the backing **31** in a non-orthogonal manner, since the sides of the extension to which attachment point **35** is connected to the backing **31** project from the backing **31** at an angle to the surface from which they extend. There is no 90° angle between the side of the extension to which the attachment point **35** is connected; on the contrary, the angle is approximately 45°, which would make the "at least one attachment point **35** extending from front side of said backing **31** in a non-orthogonal manner."

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Therefore, the prior art of record still anticipates the claimed invention and the rejection for **claims 1, 2, 13, 16, 21, 24-26 and 54** under U.S.C. 102(b) is recapitulated hereinafter.

3. Applicant's arguments, with respect to the 102(b) rejection of **claims 48 and 50** and the 103(a) rejections of **claims 11, 12 and 55-58**, filed October 25, 2004 (see pages 7-8), have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new grounds of rejection are made hereinafter.

4. Applicant's arguments, with respect to the 103(a) rejection of **claim 49**, filed October 25, 2004 (see page 9), have been fully considered but they are not persuasive. The Examiner would like to reiterate that it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Goble to be shapeable intra-operatively for use in a patient's body, as taught by Tschakaloff, for the purpose of proper fit.

5. Applicant's arguments, with respect to the 102(e) rejection of **claims 1, 2, 11-13, 21, 24-26, 46-50, 54 and 55** and the 103(a) rejection of **claims 16 and 56-58**, filed October 25, 2004 (see pages 9-10) have been fully considered and are persuasive. The 102(e) rejection of **claims 1, 2, 11-13, 21, 24-26, 46-50, 54 and 55** and the 103(a) rejection **claims 16 and 56-58** over Tormala (US 6,350,284) have been withdrawn.

Terminal Disclaimer

6. The terminal disclaimers filed on October 25, 2004 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the

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expiration date of US Patent Nos. 6,645,226 and 6,485,503, and copending application 10/418,541, has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **Claims 1, 2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement by incorporating new matter into the claims. The claims contains subject matter which was not described in the original specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the phrase "at least one attachment point extending from the front side of said backing in a non-orthogonal manner" lacks proper support in the original disclosure, and therefore, is considered new matter, which cannot be entered in an amendment.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. **Claims 1, 2, 13, 16, 18, 21, 24-26 and 54** are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. (US 5,352,229).

Regarding **claim 1**, Goble et al. discloses an implantable tissue approximation device since bone can be broadly and reasonably be interpreted to be a form of hard tissue. Nonetheless, functional language is not given patentable weight in apparatus claims and the device of Goble et al. is fully capable of performing the function. The device has a supportive backing **31** having a front side, a back side, and at least one through-hole **33, 34** formed therethrough; and at least one attachment point **35** extending from front side of the backing **31** (column 5, lines 55-68), as shown in Figure 2.

Regarding **claim 2**, wherein said backing **31** that has a shape in the form of an H, as seen in Figure 2.

Regarding **claim 13**, wherein said backing **31** comprises a solid material.

Regarding **claim 16**, wherein said at least one attachment point that includes a shape and direction selected from the group consisting of canted tines, erect tines, canted hooks, canted arrowheads, erect barbed tipped tines, canted barbed tipped tines, erect arrowhead tipped tines, canted arrowhead tipped tines, erect nail-shaped tines, canted nail-shaped tines, and cheese grater-like tines, as shown in Figure 2.

Regarding **claim 21**, wherein the at least one attachment point that includes a plurality of attachment points and wherein the at least one through-hole is disposed between the attachment points, as shown in Figure 2.

Regarding **claim 24**, wherein the supportive backing is rigid.

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Regarding **claim 25**, wherein the supportive backing has a strength sufficient to set fragmented bones (columns 5-6), as shown in Figure 2.

Regarding **claim 26**, wherein the supportive backing defines at least one through hole and includes a plurality of through-holes formed through the supportive backing, as shown in Figure 2.

Regarding **claim 54**, wherein said at least one attachment point that includes a plurality of attachment points that are interspersed among the plurality of through-holes, as shown in Figure 2.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. **Claims 8, 11, 12, 46, 47 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US 5,352,229), as applied to **claims 1, 2, 13, 16, 18, 21, 24-26 and 54** above, in view of Duncan (US 4,548,202). Goble et al. discloses a device comprising all the limitations recited in **claims 8, 11, 12, 46, 47 and 49**, with the exception of the device being produced from a biodegradable and biological material that is flexible and porous. However, the use of such a material in a medical implant device was known at the time the invention was made. Specifically, Duncan teaches the use of a mesh tissue fastener for "facilitate healing of a wound or incision" by providing "hemostatic compression to minimize bleeding, but allow some collateral

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blood circulation to the wound or incision edges of the tissue to promote healing” and allowing for the “capability to accommodated varying tissue thicknesses and...leave as little tissue cuff or margin as possible in effecting the joining of the tissue”. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Goble et al. by constructing it of a biodegradable and biological material that is flexible and porous because it is known in the art, as taught by Duncan, to use such a material in medical implant devices in order to provide a device that allows the tissue to heal while adjusting to fit into different configurations in the patient’s body.

13. **Claims 8, 46, 47 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US 5,352,229), as applied to **claims 1, 2, 13, 16, 18, 21, 24-26 and 54** above, in view of Tschakaloff (US 5,779,706). Goble et al. discloses a device comprising all the limitations recited in **claims 8, 46, 47 and 49**, with the exception of the device configured such that it is shapeable intra-operatively for use in a patient’s body. However, the use of such a medical device was known at the time the invention was made. Specifically, Tschakaloff teaches the use of intra-operatively shaped devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Goble et al. by constructing it of a material capable of being shaped during surgery because it is known in the art, as taught by Tschakaloff, to use such a material in medical implant devices in order to adjust and mold the device fit properly into different configurations in the patient’s body.

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14. **Claims 48 and 50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US 5,352,229), as applied to **claims 1, 2, 13, 16, 18, 21, 24-26 and 54** above. Goble et al. teaches a device comprising all limitations recited in **claims 48 and 50**, but does not expressly disclose that the front and back sides of the backing **31** are concavely curved. At the time of the invention was made, it was well known to form implant devices in a curved configuration in order to more closely conform to the surface of tissue it is being implanted upon. Therefore, it would have been obvious to one having ordinary skill in the art to modify the backing front and back sides to be curved in a concave configuration as Applicant has done. Moreover, Applicant has not asserted that the specific configuration recited provides a particular advantage, solves a stated problem or serves a purpose different from that of a planar, or flat, backing, thus the use of curved surface of both the front and back sides of the backing lacks criticality in its design. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a planar backing because the device would still be fully capable of setting fragmented bones or repair bodily tissue. Therefore, it would have been obvious to modify the device of Goble et al. by altering the backing to have a curved surface because it is well known in the art to use a curved surface in an implant in order to more closely fit the contour of bodily tissue or bones.

15. **Claims 55-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over **8, 46, 47 and 49** above, in view of Talpade (US 6,110,100). Goble et al. teaches a device comprising all limitations recited in **claims 55-58**, with the exception of a therapeutic agent impregnated or coated on the device. However, the use of a therapeutic agent on

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a medical implant device was known at the time the invention was made. Specifically, Talpade teaches the use of a therapeutic agent being coated on or impregnated into a medical implant device for delivery of the therapeutic agent to aid the patient in recovery (column 8, lines 13-23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Goble et al. by coating or impregnating it with a therapeutic agent because it is well known in the art, as taught by Talpade, to deliver a therapeutic agent to a patient in this manner in order to aid the patient in healing and recovery.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


17. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

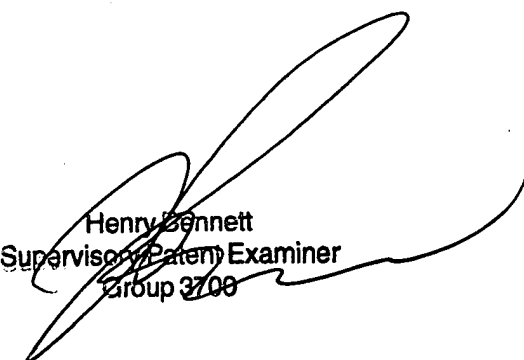
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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR 
January 21, 2005


Henry Bennett
Supervisory Patent Examiner
Group 3700